Public Citizen, Health GAP, June 16, 2011. Contact: pmaybarduk@citizen.org; b.baker@neu.edu. For more information, see www.citizen.org/access.

Dangers for Access to Medicines in the Trans-Pacific Partnership Agreement:

Comparative Analysis of the U.S. Intellectual Property Proposal and Vietnamese Law

Issue	Leaked U.S. TPPA Proposal (10 February 2011)	Vietnamese Law On Intellectual Property 50/2005	Analysis
Patent Law Treaty (2000)	Article 1.5. Each Party shall make all reasonable efforts to ratify or accede to the following agreements by the date of entry into force of the Agreement: (a) Patent Law Treaty (2000); and	*Although Vietnam participates in the WIPO meetings on the Treaty, Vietnam is not a party to the Patent Law Treaty.*	The Patent Law Treaty (PLT) is a treaty of the World Intellectual Property Organization (WIPO). It harmonizes formal procedures involved in national and regional patent applications. The requirements regarding the form of application are quite low. It has been subject to criticism for favouring patent applicants and increasing the burden on national patent offices.

			Being forced to join the PLT may reduce Vietnam's freedom to define strict standards of patentability, and avert unwarranted drug monopolies.
Patentability Requirements	Article 8.1. Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. FN15: For the purposes of this Article, a party may treat the terms "inventive step" and " capable of industrial application" as being synonymous with the terms "non-obvious" and "useful" respectively. In determinations regarding inventive step (or non-obviousness), each Party shall consider whether the claimed invention would have been	Article 58. An invention shall be protected by mode of grant of invention patent when it satisfies the following conditions: (a) Being novel; (b) Involving an inventive step; (c) Being susceptible of industrial application.	While this restatement of the TRIPS standard would not require TPPA parties to change their laws, it illustrates the differences in patent standards between the countries, and is helpful in understanding how the subsequent US-proposed provisions and patent standards would change the laws of Vietnam and other TPPA countries. Article 8.1 should be read in conjunction with Articles 8.2 and 8.12. In U.S. law and practice, 'usefulness' is interpreted broadly to cover any application, utility, or an improvement over existing products and/or techniques. "Capable of industrial application" tends to be a more precise concept, leading to higher quality patents. Treating "capable of industrial application" as synonymous with "useful" would lower patentability

	obvious to a skilled artisan (or having ordinary skilled in the art) at the priority date of claimed invention.		standards in Vietnam. Non-obviousness is a weak form of regulating "inventive step."
Industrial Application v. Utility	Article 8.12. Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility.	Article 62. An invention shall be considered susceptible of industrial application if it is possible to realize mass manufacture or production of products or repeated application of the process that is the subject matter of the invention, and to achieve stable results. ** The invention should be usefully developed and applied in an industrial or commercial context in order to be eligible for patenting in Vietnam.*	This notion of specific, substantial and credible utility is broad enough to cover inventions without true industrial application. Accordingly, any invention that has a practical application and that produces useful and specific results satisfies utility requirements. Under the U.S. proposal standard industrial application requirements could no longer be asserted as a patent bar against such types of inventions (as discussed below; compare and read in conjunction with articles 8.1 and 8.2). This would lower patentability standards.
Protection of New Forms, Uses, or Methods of using a known product	Article 8.1. The Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a	** The Vietnamese Law stays silent as to protection of new medical uses or compositions. Nevertheless, Article 4.12 defines "invention" as a*	The Vietnamese Law requires an invention to be either a product or process in order to be patented. A use or a method claim is not regarded as a

	new form, use, or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.	*technical solution in the form of a product or a process which is intended to solve a problem by application of laws of nature.* *Since the introduction of the Law on Intellectual Property in 2006, and relying on the definition of invention provided by Article 4.12, the National Intellectual Property Office (NOIP) rejects all use claims including the first medical use of a known product and Swiss-type second or subsequent use claims on the basis that they are neither product nor process.*	product or process and thus does not satisfy the criteria for patentability. Therefore, the NOIP does not provide patent protection to claims for new methods or uses – for example, new medical uses for known, older products. Under the U.S. proposal, patent protection would be extended to new forms, uses, and methods of using a known product. Pharmaceutical companies could then freely file patent applications for new methods of preparation, new formulations and new uses of known substances without being subject to restrictions. When read in conjunction with Article 8.2 (as discussed further below), second or subsequent medical uses may also be subject to patent protection in Viet Nam. The patenting of new forms, uses or methods of known products would give rise to patents on minor variations of existing chemical entities, regardless of impact on therapeutic efficacy, and risks greatly expanding

			pharmaceutical patents. This provision stands in contrast to pro-access alternatives such as that found in the India Amended Patent Act (2005), Section 3(d), which has been used to thwart minor changes and re-patenting of existing medicines to gain an extra twenty years of patent monopoly protection.
Exclusions from Patentability	Article 8.2. Each Party shall make patents available for inventions for the following: (a) plants and animals, and (b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.	Article 59. The following subject matters shall not be protected as inventions: 1. Scientific discoveries or theories, mathematical methods; … 5. Plant varieties, animal breeds; 6. Processes of plant or animal production, which are principally of biological nature other than microbiological ones; 7. **Human and animal disease prevention, diagnostic and treatment methods.** *The medical treatment exclusion from patentability applies not only to treatment and diagnostic*	Vietnam excludes diagnostic and treatment methods from patent protection; on the basis that method of treatment claims only produce effects on the human (or animal) body, and not an industrial effect as required by the Vietnamese law (industrial application). This exclusion is also grounded in ethics, i.e. to provide physicians with greater flexibility to treat patients with therapies that best fit their needs. Patentability of a new medical effect of known drugs – known as second/subsequent use – also falls within this exclusion. It is considered a

		methods on the human body, but also disease prevention procedures. *In practice, the NOIP is quite strict about method of treatment claims. The NOIP does not allow patents for method of treatment claims that have been drafted in the form of second use or Swiss-type claims.*	method for treatment of humans in Vietnam. As explained above, Article 8.1 provides patent protection to new uses and method claims. Article 8.2 makes methods of treatment for the human (or animal) body eligible subject matter for patents. Article 8.12 (as discussed above) interprets industrial application in a broad sense and seeks specific, substantial and credible utility to satisfy industrial application requirements. When read together, these three Articles assure patent protection for pharmaceutical companies claiming second or subsequent use of known products and further restrict generic competition. The new fields of health technology, e.g. biotechnology and genetic science, make extensive use of method claims in their patent applications. Such methods and procedures are usually carried out on the human body or are somehow related to treatment of the human body. The expansion of patent protection to diagnostic, therapeutic

			and surgical methods for the treatment of human beings guarantees patent protection for such types of inventions. Additionally, introduction of patentability for methods of treatment for the human body in Viet Nam without any safeguards could impose additional costs on Vietnam's healthcare system. Hospitals would be required to obtain licenses for patented treatments that they offer, and pay royalties for the patented diagnostic, therapeutic and surgical methods they use.
'Bolar' type Exemption	Article 8.5. Placeholder Provision	** There is no 'Bolar type' exemption in Vietnamese Law.*	It is desirable for Vietnam to introduce an early-working limited exception (Bolar-type), which is permissible under TRIPS Article 30 and consistent with U.S. practice.
Patent Term Restoration/Adjustment	Article 8.6. Placeholder Provision	Article 93. Invention patents shall each have a validity starting from the grant date and expiring at the end of 20 years after the filing date. ** The Vietnamese Law contains no*	As in previous FTAs, the U.S. may seek measures to extend patent terms for perceived "unreasonable delays" between the date of patent filing and the date of the patent office's decision. Patent term "restoration" significantly

		provision addressing patent term restoration or adjustment. There is no obligation to grant patent term extensions for processing periods over a certain length in patent examination and granting.	delays the entry of generic drugs into the market and thus restricts access to affordable medicines.
Third-Party Opposition	Article 8.7. (…) Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.	Article 112. As from the date an industrial property registration application is published in the Official Gazette of Industrial Property, until prior to the date of issuance of a decision on grant of a protection title, any third party shall have the right to express opinions to the concerned state management agency in charge of industrial property <u>rights on the grant or refusal to grant a protection title in respect of such application.</u> Such opinions must be made in writing and be accompanied by documents or must quote the source of information. Article 117/4. Where there appears an objection to the intended grant of a protection	The pre-grant mechanism is a safeguard against potential abuse of the patent system. The U.S. draft limits third party opposition to post-grant only. Even with post-grant opposition procedures, the absence of pre-grant opposition will make patent examination less informed, result in improvidently granted patents, and ultimately increase the number of cases before the courts. The costs associated with the patent opposition system would rise significantly. This would create market uncertainty for generics firms, and lead to weak patents and unjustified drug monopolies until post-grant challenges could reach a successful conclusion.

		title, the relevant industrial property registration application shall be re-examined with regard to the matters against which the objection is made. ** The Vietnamese patent system provides for both pre-grant and post-grant oppositions. During the examination process, any third party can file a written opposition in relation to a grant or refusal of patent rights. The pre-grant oppositions can be filed at any time between publication of the application and its grant.* *Post-grant opposition can be filed in order to invalidate a patent.*	
Protection of test data submitted for market approval	Article 9.2. Placeholder Provision	Article 128. 1. Where the law requires applicants for licenses for trading in or circulating pharmaceuticals or agro-chemical products to supply test results or any other data being business secrets obtained by investment of	Data exclusivity delays the market entry of generics and keeps drug prices unnecessarily high. Data exclusivity provisions are also inconsistent with medical ethical standards against duplicating tests on humans or vertebrate animals.

		considerable efforts, and where applicants request such data to be kept secret, the competent licensing agency shall be obliged to apply necessary measures so that such data are neither used for unhealthy commercial purposes nor disclosed, except where the disclosure is necessary to protect the public. 2. From the submission of secret data in applications to the competent agency mentioned in Clause 1 of this Article to the end of a 5-year period as from the date the applicants are granted licenses, such agency must not grant licenses to any subsequent applicants in whose applications the said secret data are used without the consent of submitters of such data, except for the cases specified at Point d, Clause 3, Article 125 of this Law. ** The Vietnamese Law provides a five**- year protection** to all kinds of data submitted for marketing approval including but not limited to*	Following U.S. law, the U.S. is likely to ask for additional three-year periods of data exclusivity when a medicine registrant seeks regulatory approval of a modified medicine or a new use of an existing medicine, if accompanied by new clinical data. The U.S. may also seek as many as twelve years of data/market exclusivity for the data related to biologics (biotech medicines). In an absolute form and without public health exceptions, data exclusivity could block the marketing of medicines produced pursuant to a lawful compulsory license or to address public health needs even in the absence of a patent.

		pharmaceutical compositions, dosage forms and new uses of a known drug, or second indications. *There is no system of automatic test data protection in Vietnam. Pharmaceutical companies are required to specifically request data exclusivity while they are applying for marketing approval. The protection only applies to new drugs utilizing new chemical entities and new combinations of known entities.*	
Patent Linkage	Article 9.3. Placeholder Provision	** The Vietnamese law contains no provision that links the patent system to the marketing approval process.* *Vietnam has previously articulated opposition to patent linkage to the European Chamber of Commerce in Vietnam.*[1]	In all recent U.S. FTAs, a provision exists for patent linkage (it is considered voluntary under the Peru-U.S. FTA). Patent linkage imposes significant administrative burdens on regulatory bodies. Patent enforcement responsibility shifts to the regulatory authorities, which have limited knowledge and experience in the issue.

[1] "Vietnam argues that it is not appropriate to inject patent enforcement procedures into regulatory procedures, and that it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents." Faunce, Thomas Alured and Townsend, Ruth, Trans Pacific Partnership Agreement - Public Health and Medicines Policies (November 7, 2010). NO ORDINARY DEAL - UNMASKING THE TRANS-PACIFIC PARTNERSHIP FREE TRADE AGREEMENT, Ch. 10, pp. 149-162, J. Kelsey, ed., Allen & Unwin, 2010. Available at SSRN: http://ssrn.com/abstract=1704834

			As with data exclusivity, patent registration linkage could block registration and marketing of medicines produced pursuant to a compulsory license.
Patent term extensions for regulatory review periods	Article 9.4. Placeholder Provision	* *Vietnamese Law does not provide patent term extension for perceived delays in the regulatory approval process.* *The U.S.-Vietnam FTA provides that the term of patent protection* ***may be extended*** *to compensate for delays in the regulatory approval process.*	Patent term extensions significantly delay the entry of generic drugs into the market and thus restrict access to affordable medicines.
Judicial and administrative presumption of patent validity	Article 10.2. (---) In civil and administrative proceedings involving patents, each Party shall provide for a rebuttable presumption that a patent is valid, and shall provide that each claim of a patent is presumed valid independently of the validity of the other claims.	**In addition to pre-grant opposition procedures, post-grant opposition is available in the form of invalidation of a patent.*	The judicial and administrative presumption of patent validity gives rise to costly and one-sided court procedures, and makes it harder to challenge even weak patents.

Compensation of damages for IP infringement	Article 12.3. Each party shall provide that: b) in determining damages for infringement of intellectual property rights, its judicial authorities shall consider, *inter alia*, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.	Article 205. Where the plaintiff can prove that an act of infringing upon intellectual property rights has caused material damage to him/her, he/she shall have the right to request the court to decide on the compensation level on one of the following bases: (a) Total material damage calculated in an **amount of money plus profit gained by the defendant as a result of an act of infringing upon intellectual property rights** where the reduced profit amount of the plaintiff has not yet been calculated into such total material damage; (b) The price of the licensing of an intellectual property object with the presumption that the defendant has been licensed by the plaintiff to use that object under a license contract within a scope corresponding to the committed infringing act;	The U.S. draft proposes use of suggested retail price or other legitimate measures of value submitted by the rights holder. This provision strongly favors the interests of the right holders. A suggested retail price is a hypothetical price. Calculations submitted by a right holder may turn out to be inflated or otherwise inaccurate and higher than existing retail prices.

		(c) Where it is impossible to determine the level of compensation for material damage on the bases specified at Points a and b of this Clause, such compensation level shall be set by the court, depending on the damage extent, but must not exceed VND 500 million. ** The law sets clear standards for calculation of compensatory damages. In practice, Vietnamese courts often calculate damages based on the plaintiff's lost sales or the defendant's profits from the infringing activity.*	
Ex-officio Border Measures	Article 14.4. Each Party shall provide that its competent authorities may initiate border measures *ex officio* with respect to	Article 216. 1. Measures to control **intellectual property-related imports and exports** include:	Special border measures that are too broad in scope or fail to include adequate safeguards can lead to customs error or right holder abuse,

	imported, exported, **or in-transit merchandise**, or merchandise in free trade zones, that is suspected of being counterfeit or **confusingly similar trademark goods**, or pirated copyright goods.	(a)Suspension of customs procedures for goods suspected of infringing upon intellectual property rights; (b) Inspection and supervision to detect goods showing signs of intellectual property right infringement. 2. Suspension of customs procedures for goods suspected of infringing upon intellectual property rights means a measure taken at the request of intellectual property right holders in order to collect information and evidence on goods lots in question so that the intellectual property right holders can exercise the right to request the handling of infringing acts and request the application of provisional urgent measures or preventive measures to secure the administrative sanctioning.	including the customs seizure of generic medicines.[2] The scope of Vietnam's special border measures provisions is far too broad; implicating patent and civil trademark claims that are entirely unrelated to any counterfeiting concerns. It is beyond the competence of customs authorities to assess infringement in such civil intellectual property disputes. Acting on this authority, customs authorities could wrongfully seize generic medicines. Meanwhile, the U.S. proposal would explicitly extend special border measures authority to products in transit through Vietnam – not only those destined for the Vietnamese market or exported from Vietnam.

[2] For further discussion of special border measure standards, see Public Citizen, Comments to the European Commission on Customs Regulation 1383/2003, May 25, 2010, *available at*: http://citizen.org/Page.aspx?pid=3458. *See also* Maybarduk, Peter. 2010. ACTA and Public Health. PIJIP Research Paper No. 9. American University Washington College of Law, Washington, DC.

		3. Inspection and supervision to detect goods showing signs of infringement of intellectual property rights means a measure taken at the request of intellectual property right holders in order to collect information so that they can exercise the right to request the suspension of customs procedures. Article 119. In case of necessity, competent state agencies may apply provisional urgent measures, measures to control intellectual property-related imports and exports, or measures to prevent and secure the administrative sanctioning according to the provisions of this law and other relevant provisions of law. *In case of infringement relating to foodstuffs for human and animals, pharmaceuticals, veterinary preparations, fertilizers, plant protection drugs, plant varieties, livestock and counterfeit goods,*	If Vietnam maintained the overly broad scope of its rule, and added actions against in transit goods, the new rule could authorize precisely the sort of wrongful seizures of generic medicines in transit that recently sparked controversy in Europe and complaints by India and Brazil to the World Trade Organization. Special border measures are best applied only to cases of wilful trademark counterfeiting and wilful copyright piracy on a commercial scale.

		custom officers may take administrative actions. *Border control measures in Vietnam are available for all IP protected goods against exports and imports, but evidently not for goods in transit.*	